

REMARKS/ARGUMENTS

In this response, claims 1-4, 6, 7, 10-15, 17-26, 28-30, 48, 49, 51, 52, 54, 55, 58, 60, and 62-85 are being canceled without prejudice, and claims 86-123 are being added. Thus, only claims 86-123 will be pending after entry of the amendment. Reconsideration and continued examination of this application is respectfully requested in view of the amendments above and the remarks below.

New claim 86 specifies a method of providing therapy to a patient, support for which can be found e.g. in original claims 1, 6, and 18, and at page 23, lines 18-30 of the specification. New claim 87 specifies that sensing the muscle tone includes sensing the muscle tone using an electromyogram sensor. Support for this can be found e.g. in original claim 7. New claim 88 specifies that sensing the muscle tone includes sensing the muscle tone using a sensor mechanically coupled to an implantable medical device. Support can be found in e.g. original claim 58. New claim 89 specifies that the sleep state informed therapy comprises a cardiac therapy. Support can be found e.g. in original claim 20. New claim 90 specifies that the sleep state informed therapy comprises a preventative therapy. Support can be found e.g. in original claim 21. New claim 91 specifies that the condition associated with the sleep-wake status of the patient comprises patient activity. Support can be found e.g. in original claim 3. New claim 92 specifies that detecting conditions related to sleep includes detecting patient activity using an accelerometer. Support can be found e.g. in original claim 4. New claims 93 and 94 specify that detecting conditions related to sleep includes detecting body posture, or that the patient is asleep or awake, respectively. Support can be found e.g. in original claims 10, 12, and 13. New claim 95 specifies that the sleep-wake status includes a patient activity signal, and classifying includes determining sleep onset by comparing the patient activity signal to a sleep threshold. Support can be found e.g. in FIG. 5 and its associated description. New claim 96 specifies that classifying also includes determining sleep offset by comparing the patient activity signal to the sleep threshold. Support can be found e.g. in FIG. 5 and its associated description. New claim 97 specifies that the condition associated with REM sleep includes an REM-modulated signal, and that classifying includes determining REM sleep onset by comparing the REM-

modulated signal to an REM sleep threshold. Support can be found e.g. in FIG. 5 and its associated description. New claim **98** specifies that the classifying also includes determining REM sleep offset by comparing the REM-modulated signal to the REM sleep threshold. Support can be found e.g. in FIG. 5 and its associated description. New claim **99** further specifies detecting a cardiac signal, and that the sleep state informed therapy includes bradycardia pacing therapy responsive to the detected cardiac signal and adapted to switch to a lower pacing rate based on the sleep state classification. Support can be found e.g. at the bottom of page 16 of the specification. New claim **100** further specifies detecting a cardiac signal, and that the sleep state informed therapy includes preventative arrhythmia therapy responsive to the detected cardiac signal and to the sleep state classification. Support can be found e.g. at the bottom of page 16. New claim **101** further specifies detecting a cardiac signal, analyzing the cardiac signal on a beat-to-beat basis, and wherein the sleep state informed therapy is responsive to the beat-to-beat cardiac signal analysis. Support can be found e.g. in FIG. 6 and its associated description. New claim **102** specifies that the method includes detecting a tidal volume of the patient's respiration, and declaring a hypopnea event if the tidal volume falls below a hypopnea threshold. Support can be found e.g. on page 17 of the specification. New claim **103** further specifies declaring an apnea event if the tidal volume falls below an apnea threshold lower than the hypopnea threshold. Support can be found on page 17 of the specification. No new matter has been added.

New claim **104** is directed to an implantable medical device suitable for implantation into a patient, support for which can be found e.g. in original claims 48 and 66, and at page 23, lines 18-30 of the specification. New claim **105** specifies that the first sensor is an electromyogram sensor. Support for this can be found e.g. in original claim 55. New claim **106** further specifies an implantable housing and that the first sensor is mechanically coupled to the housing. Support can be found e.g. in original claims 58-60. New claim **107** specifies that the classification system is disposed within the housing. Support can be found e.g. in original claim 58. New claim **108** specifies that the first sensor is positioned on the housing. Support can be found e.g. at page 25, line 27 – page 26, line 4

of the specification. New claim **109** further specifies a header mounted on the housing, and that the first sensor is positioned on the header. Support can be found e.g. at page 25, line 27 – page 26, line 4 of the specification. New claim **110** further specifies an implantable housing and a lead coupled to the housing, and that the first sensor is disposed on the lead. Support can be found e.g. at page 25, line 27 – page 26, line 4 of the specification. New claim **111** specifies that the therapy system is configured to provide cardiac therapy. Support can be found e.g. in original claim 67. New claim **112** specifies that the second sensor includes an accelerometer. Support can be found e.g. in original claim 52. New claim **113** specifies that the second sensor includes a body posture detector. Support can be found e.g. in original claim 10. New claim **114** specifies that the first sensor is configured to detect a patient activity signal, and the classification system is configured to determine sleep onset by comparing the patient activity signal to a sleep threshold. Support can be found e.g. in FIG. 5 and its associated description. New claim **115** specifies that the classification system is also configured to determine sleep offset by comparing the patient activity signal to the sleep threshold. Support can be found e.g. in FIG. 5 and its associated description. New claim **116** specifies that the first sensor is configured to detect an REM-modulated signal, and the classification system is configured to determine REM sleep onset by comparing the REM-modulated signal to an REM sleep threshold. Support can be found e.g. in FIG. 5 and its associated description. New claim **117** specifies that the classification system is also configured to determine REM sleep offset by comparing the REM-modulated signal to the REM sleep threshold. Support can be found e.g. in FIG. 5 and its associated description. New claim **118** specifies that the detector system includes a third sensor configured to detect a cardiac signal, and that the therapy system is configured to provide bradycardia pacing therapy responsive to the detected cardiac signal and to the sleep state classification. Support can be found e.g. at the bottom of page 16 of the specification. New claim **119** specifies that the bradycardia pacing therapy is adapted to switch to a lower pacing rate based on the sleep state classification. Support can be found e.g. at the bottom of page 16. New claim **120** specifies that the detector system includes a third sensor configured to detect a cardiac signal, and the therapy system is configured to provide

preventative arrhythmia therapy responsive to the detected cardiac signal and to the sleep state classification. Support can be found e.g. at the bottom of page 16. New claim **121** specifies that the detector system includes a third sensor configured to detect a cardiac signal, and that the device includes an analyzer configured to analyze the cardiac signal on a beat-to-beat basis, and that the therapy system is configured to provide therapy based on both the sleep state classification and the beat-to-beat cardiac signal analysis. Support can be found e.g. in FIG. 6 and its associated description. New claim **122** specifies that the detector system further includes a third detector configured to detect a tidal volume of the patient's respiration, and that the therapy system is configured to declare a hypopnea event if the tidal volume falls below a hypopnea threshold. Support can be found e.g. on page 17. New claim **123** specifies that the therapy system is also configured to declare an apnea event if the tidal volume falls below an apnea threshold lower than the hypopnea threshold. Support can again be found e.g. on page 17. No new matter has been added.

The new claims 86-123 are believed to be in harmony with the previous restriction requirements of record and therefore proper in this regard.

Claim Rejections - §103(a)

The Office Action rejected claims 1-4, 10-15, 17-26, 28-30, 48-49, 51-52, and 62-80 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,902,250 (Verrier et al.) in view of U.S. Publication 2005/0119711 (Cho et al.). It also rejected claims 6-7, 54-55, 58, and 60 are rejected based on 35 U.S.C. §103(a) as being unpatentable over Verrier in view of Cho and further in view of U.S. Patent 6,387,907 (Hendricks et al.).

These rejections are rendered moot in view of the cancellation of the rejected claims and the introduction of new claims 86-123 which are submitted to clearly distinguish over the cited references. For example, both independent claim 86 and 104 specify, in combination with their other respective elements, sensing a muscle tone in a pectoral region of a patient.

To the extent Applicants have not responded to any characterization by the Examiner of the asserted art or of Applicants' claimed subject matter, or to any application by the Examiner of the asserted art to any claimed subject matter, Applicants wish to make clear for the record that any such lack of response should not be interpreted as an acquiescence to such characterizations or applications. A detailed discussion of each of the Examiner's characterizations, or any other assertions or statements beyond that provided above is unnecessary. Applicants reserve the right to address in detail any such assertions or statements in future prosecution.

Conclusion

The application is submitted to be in condition for allowance, the early indication of which is earnestly solicited. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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